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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,637	08/07/2001	Lawrence J. Mamett	N-6138 RSM	2070

7590 06/17/2003

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/923,637

Applicant(s)

MARNETT ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-86 is/are pending in the application.
- 4a) Of the above claim(s) 40-86 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8, 10-22 is/are allowed.
- 6) ☒ Claim(s) 23-25 and 33 is/are rejected.
- 7) ☒ Claim(s) 26-32, and 34-39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 40-86 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Claims 1-8, 10-86 are pending and claims 1-8, and 10-39 will be examined on merits.

### ***Specification***

The disclosure objected is withdrawn in view of amendment.

### ***Claim Rejections - 35 USC § 112***

Rejection of the claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of amendment.

Rejection of claims 1-3, 5-16, 18-26, 28-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for HETE-G, PGE2-G, 6-keto prostaglandin F1alpha-G, does not reasonably provide enablement for any other metabolites is withdrawn because applicant argument is persuasive.

### ***Claim Rejections - 35 USC § 102***

Claims 23-25 and 33 remain rejected for reason of record under 35 U.S.C. 102(b) as being anticipated by Futaki et al (Dec. 1997, Inflammation Research 46: p496-502), LaPointe et al (Jan. 1998, Hypertension, Dallas, 31, 1 PART 2, p218-224), Hamiltin et al (Oct. 1997, British Journal of Pharmacology 122, PROC. SUPPL, p22P), Belvisi et al (1997, British Journal of Pharmacology 120, p910-916), or WO 98/50033 (11-12-1998). Applicant argues that the cited reference fail to teach detecting a metabolite of a COX-2 selective substrate but this argument is not persuasive because the instant specification at page 10 lines 9-11 says that "a COX-2 selective

substrate" is a substrate not significantly transformed by COX-1 but transformed significantly by a COX-2. Futaki et al for example, teach especially at Fig. 1 along with data at Fig. 2 that when a COX-2 expression is induced the various oxygenation products of AA is increased. However, when COX-2 expression is not induced, the metabolites production is significantly reduced, teaching that the substrate (AA) is significantly transformed into the metabolites by COX-2.

### ***Claim Rejections - 35 USC § 103***

Rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over Kalgutkar et al (January 18, 2000, Proc. Natl. Sci. Acad. USA, Vol. 97, pages 925-930) as evidenced by page 33744, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph of Kozak et al (Oct. 27, 2000, J. Biol. Chem. Vol. 275, pages 33744-9) in view of Felder et al (1998, Annu. Rev. Pharmacol. Toxicol. Vol. 38, pages 179-200) and further in view of WO 98/50033 (cited above) is withdrawn because applicant argument is persuasive.

### ***Allowable Subject Matter***

Claims 1-8, and 10-22 allowed.

Claims 26-32, and 34-39 are objected because they depend on the rejected base claim.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1642


Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

June 14, 2003

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
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